



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration  
College Park, MD 20740

1044 5 MAY 16 P2:24

FEB 4 2005

Mr. Martin J. Hahn  
Hogan & Hartson, L.L.P.  
Columbia Square  
555 Thirteenth Street, NW  
Washington, DC 20004-1109

Dear Mr. Hahn:

This letter acknowledges receipt on January 21, 2005, by the Food and Drug Administration (FDA) of the nutrient content claim notification you submitted pursuant to Section 403(r)(2)(G) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 343(r)(2)(G)). The notification is informing FDA that Martek Biosciences Corporation intends to make nutrient content claims based upon authoritative statements of the Institute of Medicine. The nutrient content claims are for foods and dietary supplements containing alpha-linolenic acid (ALA) and docosahexaenoic acid (DHA).

The notification is undergoing FDA review. In accordance with Section 403(r)(2)(G) of the act, within 120 days (ending on May 21, 2005) of receipt of your nutrient content claim notification, you will be informed by FDA if the notification does not comply with Section 403(r)(2) of the act. A lack of action by FDA within the 120-day period will deem the proposed nutrient content claims approved and will allow a food or a dietary supplement with a label containing the claims to be introduced into interstate commerce.

If you have any questions concerning this notification, please feel free to contact me at (301) 436-1450.

Sincerely yours,

Tomoko Shimakawa, Sc.D.  
Nutrition Programs and Labeling Staff  
Office of Nutritional Products, Labeling  
and Dietary Supplements  
Center for Food Safety  
and Applied Nutrition

2005P-0189

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